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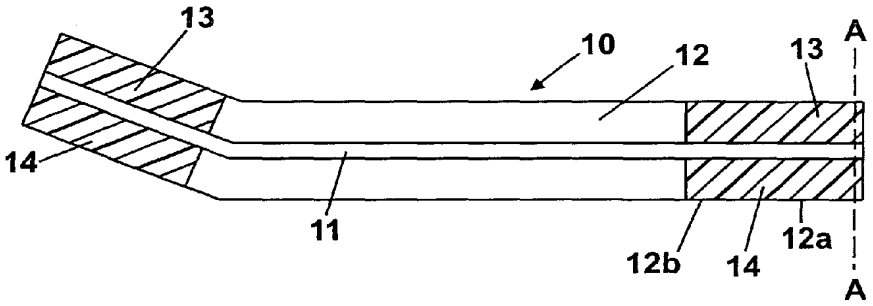

(57) Abstract: An intramedullary rod (10) for the fixation of a bone fracture or osteotomy has at least two portions (12a, 13) of differing radio density at either longitudinal end region of the rod. The portions of differing radio density allow regions into which fixation screws can be inserted to be easily identified using x-ray imaging, hi one embodiment, the rod has a main body (12) formed of titanium and portions (13) of polymeric material (13) are located in slots formed at either end of the body. The polymeric material has a different radio density to the titanium and can be drilled in situ to accept fixing screws, hi another embodiment (Figure 6), a central layer of polymeric material (213) extends the length of the rod between two casing portions of titanium (212a). In a further alternative embodiment (Figure 7) the rod (310) comprises two casing portions (312a) of solid metal and a central mesh (313) of the same material.

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INTRAMEDULLERAY FIXATION DEVICE

The present invention relates to an intramedullary fixation device for keeping broken bones supported whilst they grow back together. More specifically, but not exclusively, the invention relates to an intramedullary rod for use in supporting broken bones following a fracture or osteotomy.

Often the tendon or arrangement of tendons in proximity to a fractured bone mean that it is difficult for the bone to be fixated by surgery without causing damage to one or more of the surrounding tendons.

For example, in the hand the proximal phalanges have an associated deep flexor tendon intimately related to a superficial flexor-tendon which both lie under the phalanx. Another tendon lies above the phalanx. It is important that these tendons are regularly mobilised to prevent any fibrous adhesions forming between the tendons and which may impair movement of the finger. It is therefore advantageous that the finger is mobilised as soon as possible after the fracture which some of the known methods of treating the fracture do not allow.

Known methods of treating fractures in the proximal phalanges may involve the splinting of the bones and joints on the exterior of the finger. Although this means the bones of the fracture are supported and kept in alignment, movement of the finger is restricted by this method and because the tendons are not being moved fibrous adhesions may form leading to stiffness of the finger when the splint is removed. Physiotherapy after the splint is removed can help ease stiffness in the finger although in many cases full mobility may not be restored.

An alternative method is to use transfixing wires, such as K-wires intramedullarly across the fracture. The use of K-wires is more stable than using a splint however since the wires may extend over a joint in the bone the movement of the joint is still restricted and the same problems of stiffness of the finger as previously described may be experienced. In addition surgery is required to insert and then later remove wires from the hand.

Another known method is the use of a plate and screws fixator. Under surgery a plate is placed on the surface of the bone over the fracture and screws are placed

through the plate and bone on either side of the fracture to hold the plate in place across the fracture. The screws are usually driven into the bone in a direction substantially perpendicular with respect to the plane of the surface of the bone. The problem associated with this method is that it is difficult to know how far to insert the screws into the bone. If they are inserted too far they protrude through to the other side of the bone and there is a risk they may rupture the sheaths of the underlying tendons, or the tendons themselves. Damage to the tendons may result in stiffness or loss of function of the finger. If the screws are not inserted sufficiently far the plate will not be firmly attached to the bone to keep the fracture fixated. Since the plate lies on the surface of the bone it must be inserted under the overlying tendon, which can be difficult and time consuming to do in surgery and again risks damage to the tendon. Indeed the tendon is often intentionally split to facilitate placement of the plate. The surgery to fix the plate requires that an incision the length of the plate is made in the skin, which is undesirable since the healing of the skin impairs movement of the finger and may lead to scarring. Further it may be necessary that the plate is later removed, which would require additional surgery.

The problems outlined above which are experienced in fractures in the proximal phalanges are also experienced in other areas of the body, for example the wrist where small bones are in very close proximity to tendons and are at a risk of being damaged during fixation of the fracture.

In larger bones, such as the tibia, fractures may be fixed using an intramedullary rod. Typically, for the treatment of a fracture in the tibia a guide wire is inserted through and along the fractured bone from a location below the knee joint. A reamer is then inserted to widen the hole through the bone and an elongate rod having a series of apertures near both ends of the rod is pushed through the hole in the bone across the fracture. After removing the guide wire and reamer, a jig moveable around the exterior of the leg is fitted to the top end or proximal end of the rod, which is the end nearest the knee, to assist with the insertion of screws through the rod and bone to fixate the rod. Under x-ray, the surgeon attaches the jig to align the holes in the jig with the apertures near the top end/proximal end of the rod. The screws are then inserted from the exterior of the skin through the holes in the jig which guides the

screws through the apertures in the rod and into the bone. For the apertures near the bottom end, or distal end of the rod the jig is not a useful device because it tends to sag and thus the holes in the jig do not correspond with the apertures in the rod. A jig can only be used accurately along a certain distance of the rod from the top end, or proximal end of the rod. Typically, this distance is three times the diameter of the rod. The surgeon therefore has to drill holes in the bone free hand under x-ray control for affixing the distal end to the bone. Sometimes a targeting device with concentric circles together with a radiolucent drill is used to facilitate this difficult task. The screws must be inserted through the apertures perpendicular to the apertured surface of the rod. Even with the assistance of the targeting device and radiolucent drill it is no simple task and can be time consuming to align and insert the screws correctly into the apertures of the rod which is not desirable to the patient or the surgeon.

It has been proposed in WO 00/61018 (Depuy Orthopaedics, Inc) to provide an intramedullary nail or rod with opposing dynamization windows near the distal end into which a bio-resorbable spacer can be positioned. Screws are inserted into holes in the proximal end of the rod in the usual way whilst the distal end of the rod is secured using a bone fastener which is screwed into the spacer. As resorption of the spacer occurs, stress is increasingly transmitted through the fracture site rather than through the rod. Such arrangements are reliant on the spacer being positioned in a window formed in the nail so as to be surrounded on all four sides by the metallic material of the nail and on the use of a bi-resorbable material for the spacer. Bone healing is un-predictable and is dependent upon several factors like the age of the patient, extent of disruption of the bony and soft tissues, status of blood supply, infection etc. not all of which can be accurately predicted at the time of initial treatment of the fracture. Therefore, although a useful concept in theory, such a device is rarely used in clinical practice because it is impossible to predict the precise amount of time required for the healing to take place and to match that with the time for resorption of the bio-resorbable material filling the window.

An object of the present invention is to provide a means for the intramedullary fixation of bone fractures which mitigates or overcomes the problems associated with the aforementioned fixation techniques.

It is a further objective of the invention to provide an intramedullary rod which overcomes or at least mitigates some or all of the aforementioned problems with the prior art.

In accordance with a first aspect of the invention, there is provided an intramedullary rod for the fixation of bone fractures, wherein each longitudinal end region of the rod comprises at least two portions of differing radio density.

Each longitudinal end region of the rod may comprise two portions having a first radio density separated by a third portion having a second radio density different from the first.

The rod may comprise a body formed of a material having a first radio density, said body having a longitudinal slot in either end, each of said slots containing a material having a second radio density different from the first. Each of the slots may extend laterally across the full width of the body such that the material contained in the slot is exposed at opposing lateral surfaces of the rod.

The rod may comprise at least two spaced, elongate casing portions, the casing portions partially surrounding a central portion having a radio density different from the casing portions. The central portion may be exposed at opposing lateral surface regions of the rod between the casing portions. The casing and central portions may extend the full length of the rod.

One of said at least two portions may be substantially radiolucent and another of said at least two portions may be substantially radiopaque. The one of said at least two portions may comprise a polymeric material. The one of said at least two portions may comprise a biodegradable material. The another of said at least two portions may comprise a metal, preferably titanium.

The at least two portions may comprise the same material, the at least two portions having differing structures. One of the portions may comprise a mesh and another of the portions may comprise the same material in a form having a higher radio density than the mesh. The material in the another portion may be substantially solid.

Where, the rod comprises at least two spaced, elongate casing portions partially surrounding a central portion having a radio density different from the casing portions, the spaced, elongate casing portions may be substantially solid and the central portion may comprise a mesh of the same material. The spaced casing portions may be interconnected by a reinforcing structure which may comprise a plurality of beams which interconnect the spaced casing portions. The beams may be formed of the same material as the casing portions and the mesh. The beams may be shaped so as to correspond with part of a double helix running the length of the rod. The spaced casing portions may be arcuate when viewed in lateral cross section, the beams interconnecting opposing arcuate ends of the casing portions. The mesh may be exposed at opposing lateral surface regions of the rod between the arcuate ends of the casing portions and the beams. The material may be metallic, such as titanium or stainless steel.

In accordance with a second aspect of the invention, there is provided an intramedullary rod comprising two spaced, elongate casing portions interconnected by a portion having a lower density than the casing portions.

The lower density portion may be a mesh.

The casing portions may be further interconnected by means of a reinforcing structure. The reinforcing structure may comprise a plurality of beams. Each of the beams may be shaped so that they correspond with part of a double helix running the length of the rod. The casing portions and the mesh may comprise the same material. The casing portions, the mesh and the reinforcing structure may all comprise the same material and may be formed integrally with one another. The spaced casing portions may be arcuate when viewed in lateral cross section and the beams may interconnect opposing arcuate ends of the casing portions. The mesh may be exposed at opposing lateral surface regions of the rod between the arcuate ends of the casing portions and the beams.

In accordance with a third aspect of the invention, there is provided an intramedullary rod formed entirely of non bio-absorbable materials and having at least one region that can be drilled whilst the rod is positioned intramedullary. The at least

one region may comprise a portion of the rod having a lower density that at least one other portion of the rod. The region may extend the length of the rod.

In accordance with a fourth aspect of the invention, there is provided an intramedullary rod having no predrilled holes for receiving fixation members and a region extending along its length adapted so that one or more holes for receiving fixation members can be formed therein when the rod is positioned intramedullary.

In an intramedullary rod in accordance with any of the first, second, third or fourth aspects of the invention, the outer profile of the rod may be substantially circular or oval when viewed in lateral cross section.

In an intramedullary rod in accordance with any of the first, second, third or fourth aspects of the invention, the rod may be provided with a bore which extends lengthwise of the rod.

In an intramedullary rod in accordance with any of the first, second, third or fourth aspects, the rod may be a fixator for a proximal phalanx.

In accordance with a fifth aspect of the invention, there is provided a method of forming an intramedullary rod in accordance with the second, third or fourth aspects of the invention, the method comprising forming the rod from powdered metal using selective laser melting.

In accordance with a sixth aspect of the invention, there is provided a method of implanting an intramedullary rod across a break in a bone, the method comprising forming at least one hole in the rod whilst it is positioned intramedullary. The at least one hole may be formed using a laser, which may be an ultra short pulse laser.

Several embodiments of the invention will now be described, by way of example only with reference to the following drawings in which:

Figure 1 shows a longitudinal cross section of a fractured proximal phalanx fixed with a known arrangement of plate and screws;

Figure 2 shows a transverse cross section of the bone of Figure 1 along lines XX of Figure 1;

Figure 3a is a longitudinal cross sectional view of a fixator in accordance with the invention;

Figure 3b shows a transverse cross section of the fixator along line AA of Figure 3a;

Figure 4 is a longitudinal cross sectional view of the fixator of Figure 3 inserted within a fractured bone;

Figure 5 is a perspective view of a second embodiment of a fixator in accordance with the invention;

Figure 6 is a longitudinal cross section though a third embodiment of a fixator in accordance with the invention;

Figure 7 is a perspective view of part of a fourth embodiment of a fixator in accordance with the invention;

Figure 8 is a perspective view of a section of a mesh and reinforcing structure forming part of the fixator of Figure 6, shown in an enlarged scale; and,

Figure 9 is a view similar to that of Figure 7 showing a modification to the fixator of Figure 7.

In the following description, the same reference numbers, but increased by 100 in each case, will be used to identify features that are the same or which perform substantially the same function in each of the embodiment.

Figure 1 shows a longitudinal cross sectional view of a known means of fixing a fracture in the hand of a proximal phalanx 1. The drawings show a simplified sketch of the tendon and bone arrangement in the fractured proximal phalanx as seen from the side of a finger. Above the fractured bone 3 there is a tendon 2 and below the fractured bone 3 there are two tendons 4. Once the broken bone has been manipulated so that the two parts are aligned, a plate 5 is affixed across the fracture along the top surface 3a of the bone by means of screws or pins 6. The plate 5 is fitted under the tendon 2 during surgery which can be tricky and time consuming. Using x-ray imaging, screws or pins 6 are inserted through apertures (not shown) in the plate 5 and bone 3 either side of the fracture to fixate the plate to the bone. The screws or pins 6

are inserted in a direction substantially perpendicular with respect to the apertured surface of the plate 5. If the screws/pins 6 extend too far through the bone 3 so that the tendons 4 or sheaths of the tendons (not shown) are damaged by the pins or screws, stiffness and possible loss of function of the finger can result.

Figure 2 shows a transverse cross section of the phalanx along line XX of Figure 1. Here the plate 5 is shown attached to the bone 3 by screws/pins 6. The screws/pins are inserted perpendicular to the surface of the bone as in Figure 1. In this arrangement they could potentially damage the underlying tendons if they are too long.

Figure 3a shows a longitudinal cross section of an intramedullary fixator in accordance with the invention, whilst Figure 3b shows a transverse cross sectional view of the end of the rod 10 taken along line AA of Figure 3a. The fixator comprises a cylindrical rod or nail 10. The rod is shown in Figure 3 with one end region being angled with respect to the remainder of the rod. However, the rod may be straight or otherwise depending on the bone into which it is to be inserted. The rod 10 has a cannula or bore 11 which extends lengthwise of the rod and allows the rod to be threaded over a guide wire and reamer when inserted into the bone.

The rod has a body 12 formed from a bio-compatible material such as titanium or stainless steel. At each end region the rod has a portion of material 13 of a radiodensity different from that of the body. In the present embodiment, each portion of material 13 is located within a slot 14 which extends longitudinally into the rod for a distance from respective end to leave opposing portions 12a of the body as shown in Figure 3b. Each slot 14 extends diametrically across the full width of the rod so that the portion of material 13 is exposed at diametrically opposed surface positions 12b between the portions 12a of the body.

The slots 14 may be machined into the body 12 during manufacture or the body 12 may be produced with the slots 14 by means of moulding, or otherwise. The slots 14 are filled with a material 13 having a radio density different than that of the material of the body, such as a polymeric material, for example a high density plastics material or bio soluble polymer. Suitable materials include ploylactic acid, polyglactic acid, or composites of either with hydroxyappatite, for example. This may be

achieved by dipping or pouring a molten polymer material into the slots 14 and allowing the polymeric material to harden, or injection moulding of the polymer into the metal body enclosed in a mould. Preferably, the material of the body 12 is porous so that molten polymer flows into the pores and is firmly held within the slots when it hardens. If the body 12 is produced from a non-porous material, the inner surfaces of the slots 14 may be roughened, or appropriately shaped to allow the polymer to stick and be firmly retained within the slots 14. The bore 11 is then been produced lengthwise through the rod 10 passing through the body 12 and the portions of polymeric material 13 at either end. Further slots could be formed at each end and be filled with a polymeric or other material if required. Furthermore, rather than producing slots, enclosed openings may be formed through the body 12 in regions close to each longitudinal end and a portion of material 13 of contrasting radio density introduced into the windows.

Figure 4 is a longitudinal cross sectional view of the fractured bone 3 with the fixator rod 10. To position the rod 10, a guide wire is first inserted into the bone by known methods used in surgery for inserting intramedullary fixators. Typically, a small incision is made through the skin and the top tendon (extensor tendon), not shown into the fractured bone 3 and a guide wire inserted through the fractured bone across the fracture and into the other part of the fractured bone. A reamer is then inserted over the guide wire to widen the holes through the bone. The fixator rod can then be inserted into the holes in the confronting ends of the bone across the fracture and orientated such that the rod 10 is positioned with the opposed regions 12b at which the polymeric material 13 is exposed are aligned laterally of the bone as shown in Figure 4. The reamer and guide wires are removed.

The fixator rod then needs to be fixed in place by means of screws, pins or staples 16. For ease of reference, the following description of this and other embodiments will refer to the rod being fixed by means of screws but it should be understood that other means of fixation such as pins and staples can be used instead. Under x-ray imaging the polymer filled portion 13 which is radiolucent compared to the body 12 will show up as a darker region between whiter regions of the portions 12a of the body 12, clearly indicating to the surgeon where the screws may be

inserted. Since there are no tendons on the side of the finger where the screws are to be inserted, the surgeon can simply insert the screws through the skin and bone from each side of the finger into the polymeric area of the rod to secure the fixator to the bone.

With the prior art method previously described, the fixator was provided with apertures and the surgeon had to insert the screws into the apertures in a direction substantially perpendicular with respect to the apertured surface of the rod which proved time consuming and in case of small bones, extremely difficult. With the present invention, it is not necessary that the polymeric material has apertures to receive the screws since the screws can be driven into and retained within the polymer or the polymer can be drilled to accept the screws in situ. The polymer, owing to its contrasting radiodensity with the material of the body, is clearly identifiable on an x-ray image as a darker area (shown in Figure 4 with hatching) enclosed by two lighter areas (walls of the rod 12a, which are shown unshaded in Figure 4). As viewed under x-ray by the surgeon from the side of the finger, the walls of the rod 12a and the polymeric portion 13 have the appearance of a sandwich, the polymeric portion 13 being a central layer sandwiched between an upper and lower layer of the walls of the rod 12a. The surgeon's task of inserting the screws through the rod and bone is made easier since the surgeon has a large region which is easily identifiable in the rod in which to insert the screws as compared with known apertured fixators. Indeed, because there is a large region in which to insert the screws and the polymeric material can firmly retain the inserted screws, the screws need not be inserted perpendicularly with respect to the surface of the rod as was the case with the methods previously described. The screws can be inserted obliquely into the polymer portion 13 and still firmly fixate the rod. The overall surgery time for fixing the rod is less than that for fixing known apertured fixators.

Since only a small incision is made in the skin and tendon to insert the guide wire, reamer and rod into the bone, the healing of the skin and the tendon is quicker which allows the finger to be mobilised soon after surgery.

The fixator rod 10 can be left in the body as the bone will grow over it. This reduces the need for further surgery. However, it may also be advantageous to coat the

outer surface of the rod with a biologically inert material, such as Teflon (RTM) PTFE, to prevent bony in-growth into the rod. This would facilitate removal of the rod at a later date if so desired. Intramedullary fixation devices mean movement of the finger can be commenced almost immediately after surgery thus reducing stiffness of the finger.

Whilst the polymeric materials are particularly suitable for use in providing portions of contrasting radio density, it should be understood that other materials could be used. However, the radio density of the material 13 should be sufficiently different from that of the body 12, that the portions 13 can be readily distinguished from the body 12 when viewed using x-ray imaging.

It is a particular advantage of the fixator in accordance with the invention that both ends of the rod comprise a polymeric portion 13 of contrasting radio density into which the pins or screws can be inserted and which are easily identifiable using x ray imaging. The comparatively large area of the polymeric portions into which the screws can be fitted, compared with the pre-drilled holes found in the prior art, combined with the fact that the screws need not be inserted perpendicularly to the surface of the rod means that there is a higher margin of error of screw placement. This enables a jig to be used for screw placement at both the proximal and distal ends. The lengths of the polymeric portions can be varied to suit the requirements of the bone to be fixed. Figure 5, illustrates a further embodiment of a fixator rod 110 in accordance with the invention in which the slots 114 and the portions of polymeric material 113 extend from each longitudinal end to a position close to the centre of the rod. This provides a very large target area into which the pins or screws can be inserted.

Figure 6 illustrates an alternative embodiment of a fixator rod 210 in which, rather than having two discrete portions of polymeric material at either end, a single portion of polymeric material 213 extends the entire length of the rod. In this embodiment, the rod 210 is formed as a laminate having two spaced elongate layers or casing portions 212a of titanium, stainless steel or other suitable material bonded to either side of a central portion 213 of polymeric material. The rod 210 is circular in

lateral cross section so that the casing portions 212a of titanium are arcuate, similar to the end portion 112a shown in Figure 5.

An intramedullary rod 210 which has a portion 213 of differing radio density into which a fixing screw can be inserted that extends the whole length of the rod can be advantageously used in conjunction with a lag screw to reduce a fracture or osteotomy.

Lag screws are used to reduce an oblique fracture or osteotomy by drawing the two sections of bone together under compression. Typically, a clearance bore is drilled through one section of bone and a smaller diameter bore is drilled in the other section of bone. A lag screw is inserted through the clearance bore, across the break and is screwed into the smaller diameter bore formed in the other section of bone. The lag screw is then tightened to draw the two sections together, reducing the fracture or osteotomy. Whilst a single lag screw is useful for holding the two sections of bone in compression, it is unable to resist rotational forces. Thus a lag screw is usually used in combination with device to neutralise rotational forces. One example of a neutralisation device is a side plate which is fixed to the exterior of the bone sections across the fracture site with all the attendant difficulties discussed previously.

Advantageously, an intramedullary rod 210 in accordance with the invention having a continuous polymeric portion 213 can be used in conjunction with a lag screw to resist relative rotation of the bone sections. The rod 210 is inserted across the fracture site and a lag screw inserted to reduce the fracture, with the lag screw passing through the polymeric material 213 in the rod. The end regions of the rod can then be fixed to their respective bone sections as described previously to resist rotational forces. In some cases, it may be preferable to fix one end region of the rod 210 to its respective bone section before the lag screw is inserted. Because the polymeric portion 213 extends over the whole length of the rod 210, the surgeon has a high degree of freedom in positioning the rod, the lag screw and fixation screws or pins. This method of combining a 'lag screw' for providing stability and compression at the fracture site and an intramedullary device locked at either end to prevent flexural as well as rotational stability is possible because of the unique design of the rod 210 with a continuous polymeric layer though which it is possible to drill at an oblique angle.

One limitation on the use of the rod 210 is the ability of the polymeric material 213 to resist torsion. Many polymeric materials have relatively low torsional strength which may limit its use. To improve the torsional strength of the rod, a co-polymer and/or a fibre reinforced polymeric material can be used. For example, the polymeric material 213 may be reinforced by means of fibres or the like arranged in a criss-cross pattern. The material may be a carbon fibre composite or other composite material. Fibre reinforcement of polymeric materials is generally well known in other fields. Whilst the presence of the fibers increases the torsional strength of the polymeric or other material, the material as a whole will still be radiolucent in comparison with material in the casing portions and thus can be easily distinguished using x-ray imaging.

Figures 7 & 8 illustrate a further alternative embodiment of an intramedullary rod 310 which is designed to overcome the limitations of the previous embodiment. In the rod 310, the portions of contrasting radio density are not produce by incorporating different materials. Rather, the same material is used throughout but the structure is changed to produce regions of contrasting radiodensity.

The rod 310 comprises two spaced, elongate layers or casing portions 312a. The volume between the casing portions is filled by a porous mesh 313 produced from the same material as the casing portions 312a. The casing portions 312a are substantially solid and so relatively dense when compared with the mesh 313. Preferably, the casing portions 312a and the mesh 313 are produced from a bio-compatible material. It is particularly advantageous if the casing portions and mesh are produced from a bio-compatible metallic material such as titanium or stainless steel. The substantially solid casing portions 312a and the porous mesh will be clearly distinguished from one another other when viewed using x-ray imaging owing to the differences in radio density between the regions. The size of the mesh can be selected as appropriate to the application but in one embodiment the mesh is comprised of filaments having a diameter of about 100μm and which are spaced by 100μm to 500μm (microns).

The porous mesh 313 is able to receive fixing screws which can be screwed directly into and held by the mesh 313. Alternatively, holes may be drilled or

otherwise formed in the mesh to receive the screws whilst the rod is in situ. However, it is an advantage that the holes can be formed at any desired angle and need not extend perpendicularly to the surface of the rod as in the prior art. With a conventional intramedullary rod or nail with a solid metallic body, it is not possible to drill holes in the rod whilst it is in-situ intramedullary because too much heat and debris is generated. However, because the mesh 313 is of a lower density than the solid material used in the prior art rods, holes can be formed in the mesh without generating unacceptable levels of heat or debris.

The rod 310 is circular in lateral cross-section and the spaced casing portions 312a are arcuate. To increase the torsional strength of the rod 310, a reinforcing structure is also provided. In the present embodiment, the reinforcing structure comprises a plurality of beams 320 which interconnect opposing arcuate end regions 312c of the casing portions 312a. The beams 320 are considerably thicker than the wires or filaments that make up the mesh 313 and give added structural rigidity to the rod. In a particularly advantageous arrangement, the beams are shaped to form part of a double helix running the length of the rod. Figure 8 shows the rod 310 with the casing portions removed so that the mesh and the doubly helix configuration of the beams can be seen. The double helix configuration is particularly beneficial in resisting torsion.

The mesh 313 fills the core of the rod between the casing portions 312a as well as the spaces or windows 312b between the opposing arcuate ends 312c of the casing portions and the reinforcing beams 320. The casing portions 312a and beams 320 are arranged so that windows 312b are provided in alignment on either side of the rod in diametrically opposing positions. When viewed using x-ray imaging, the mesh filled windows will be clearly distinguished from the casing portions and the beams allowing the surgeon to position the rod and insert fixing screws into the mesh through an appropriate window. Where the rod 310 is to be used in conjunction with a lag screw to reduce a fracture or osteotomy, a bore can be formed through the mesh portion of the rod for the lag screw, the bore entering and exiting via windows 312b on either side.

The shape of the windows 312b is determined by the size and spacing of the casing portions and/or their position on the circumference relative to the double helix configuration of the reinforcing beams. In the embodiment shown in Figure 7, the casing portions are aligned relative to the double helix so that the windows 312b coincided with the point at which the helixes cross one another. Figure 8 illustrates a modified embodiment of a rod 410 in which the position of the casing portions 412a has been moved relative to the double helix so that the windows align with a mid-point where the spacing between the helixes is at its maximum. By comparing Figures 6 and 8, the effect of re-positioning the casing portions 312a, 412a relative to the double helix on the shape and number of the windows 312b, 412b can be seen. Thus in the Figure 7 embodiment, the rod 310 has a fewer number of longer, generally rectangular shaped windows 312b. In contrast, the rod 410 as shown in Figure 8 has an increased number of shorter windows 412b which have a truncated triangular shape.

The intramedullary rods 310, 410 as described above in relation to Figures 6 to 8 can be manufactured from powdered metal using selective laser meting or selective laser sintering. Selective laser melting is a known process by which metal powder is melted by an intensive infrared laser beam to form a desired geometry layer by layer. Preferably, the metallic powder is bio-compatible such as titanium or stainless steel. By using this method of manufacture, the casing portions, mesh and reinforcing beams are constructed from the same material as an integral component providing increased structural integrity.

Intramedullary rods in accordance with the invention can be produced in a range of sizes depending on the size of bones with which they are to be used. For an intramedullary rod for use in fixating the phalanx, a rod having a diameter of 3mm would be typical though the diameter could be in the range of 2 to 4mm. In a rod 310, 410 as described above having a diameter of 3mm, the casing portions would typically have a thickness of 0.5mm and the beams forming the reinforcing structure have a thickness of 0.5mm, the same as the casing portions. The double helix on which the beams are positioned have a pitch of 3mm with a 2.5mm gap at the widest part.

One of the problems encountered with the use of small intramedullary rods is the difficulty of drilling through them mechanically as there is a tendency for the drill bit to jump. Additionally, debris is produced which may provoke a foreign body reaction in the patient's body. To address this problem, it is proposed that the rods be drilled using a laser. Use of an optical drill rather than a mechanical drill bit means there is no risk of jumping and damaging the surrounding bone or tissue or the rod itself. Any suitable laser can be used including Erbium, YAG, Infrared or CO2 lasers for example. However, it is preferred that the laser is an ultra short pulse laser rather than a continuous wave laser because less heat is generated and transferred into the target and surrounding material. A further advantage of using ultra short pulse laser is that the spectral characteristics of the plasma emission generated by a material as it vaporises can be analysed to differentiate between different materials using a spectroscope. Thus emitted light from the plasma can be collected and analysed by a spectroscope to provide feedback control of the laser to ensure that only the target materials are removed. The device can, therefore, be calibrated to differentiate between bone, the rod and surrounding tissue. For example, when forming a bore for a lag screw, the device can be controlled so that it produces a bore through the first bone section, the mesh region and the second bone section only.

Use of ultra short pulse laser for optical dental drilling has been proposed in US patent No. 5720894 assigned to the Regents of the University of California. The reader should refer to this document for a more detailed explanation of the process and feedback control using spectral analysis. The contents of this patent are hereby incorporated by reference.

One of the advantages of an intramedullary rod 310, 410 in accordance with the last described embodiment is that it can be formed from a single bio-compatible material such as titanium or stainless steel. Such materials have been used in intramedullary devices for many years and are known to be safe and so are trusted by many surgeons. However, it would be possible to replace the mesh 313, 413 with a polymeric or other material if desired. In this arrangement, the casing portions and reinforcing beams could be manufactured from a bio-compatible metallic material, such as titanium or stainless steel, by selective laser melting and the polymeric or

other material introduced later. The reinforcing structure in this case would help to ensure the rod had sufficient torsional strength.

As discussed previously, the rod 310 may be coated with a biologically inert material such as Teflon (RTM) PTFE to prevent bony in-growth into the rod and in to the mesh in particular.

The intramedullary rods described herein are circular in lateral cross-section but it should be appreciated that other shapes can be used. For example the rod could be oval or ovoid in lateral cross section.

The phalanx has been used as an example of the type of bone which may benefit from the invention, however, it must be understood that the invention can also be used in other bones, for example wrist, forearm, arm and shoulder bones where it is necessary that precise insertion of fixing pins through the bone and fixator is required. Although the body preferably comprises porous titanium, other suitable materials could be used.

Whereas the invention has been described in relation to what is presently considered to be the most practical and preferred embodiment, it is to be understood that the invention is not limited to the disclosed arrangements but rather is intended to cover various modifications and equivalent constructions included within the spirit and scope of the invention.

Claims

1. An intramedullary rod for the fixation of a bone fracture or osteotomy, wherein each longitudinal end region of the rod comprises at least two portions of differing radio density.

2. An intramedullary rod as claimed in claim 1, wherein each longitudinal end region of the rod comprises two portions having a first radio density separated by a third portion having a second radio density different from the first.

3. An intramedullary rod as claimed in claim 1 or claim 2, in which the rod comprises a body formed of a material having a first radio density, said body having a longitudinal slot in either end, each of said slots containing a material having a second radio density different from the first.

4. An intramedullary rod as claimed in claim 3, in which each of the slots extends laterally across the full width of the body such that the material contained in the slot is exposed at opposing lateral surfaces of the rod.

5. An intramedullary rod as claimed in claim 1 or claim 2, in which the rod comprises at least two spaced, elongate casing portions, the casing portions partially surrounding a central portion having a radio density different from the casing portions.

6. An intramedullary rod as claimed in claim 5, in which the central portion is exposed at opposing lateral surface regions of the rod between the casing portions.

7. An intramedullary rod as claimed in claim 5 or claim 6, in which the casing and central portions extend the full length of the rod.

8. An intramedullary rod as claimed in any preceding claim, in which one of said at least two portions is substantially radiolucent.

9. An intramedullary rod as claimed in any preceding claim, in which another of said at least two portions is substantially radiopaque.

10. An intramedullary rod as claimed in claim 8 or claim 9 when dependent on claim 8, in which the one of said at least two portions comprises a polymeric material.

11. An intramedullary rod as claimed in claim 8 or claim 10, in which the one of said at least two portions comprises a biodegradable material.

12. An intramedullary rod as claimed in claim 9, or either of claims 10 and 11 when dependent on claim 9, in which the another of said at least two portions comprises a metal, preferably titanium.

13. An intramedullary rod as claimed in any one of claims 1 to 8, in which the at least two portions comprise the same material, the at least two portions having differing structures.

14. An intramedullary rod as claimed in claim 13, in which the at least two portions comprise regions of differing density.

15. An intramedullary rod as claimed in claim 13 or claim 14, in which one of the at least two portions comprises a mesh and another of the portions comprises the same material in a form having a higher density than the mesh.

16. An intramedullary rod as claimed in claim 15, in which the material in the another portion is substantially solid.

17. An intramedullary rod as claimed in and one of claims 5 to 7, in which the spaced, elongate casing portions are substantially solid and the central portion comprises a mesh of the same material.

18. An intramedullary rod as claimed in claim 17, in which the spaced casing portions are interconnected by a reinforcing structure.

19. An intramedullary rod as claimed in claim 18, in which the reinforcing structure comprises a plurality of beams which interconnect the spaced casing portions.

20. An intramedullary rod as claimed in claim 19, in which the beams are formed of the same material as the casing portions and the mesh.

21. An intramedullary rod as claimed in claim 19 or claim 20, in which the shape of the beams corresponds with part of a double helix running the length of the rod.

22. An intramedullary rod as claimed in any one of claims 18 to 21, in which the spaced casing portions are arcuate when viewed in lateral cross section, the beams interconnecting opposing arcuate ends of the casing portions.

23. An intramedullary rod as claimed in claim 22, in which the mesh is exposed at opposing lateral surface regions of the rod between the arcuate ends of the casing portions and the beams.

24. An intramedullary rod as claimed in any one of claims 17 to 23, in which the material is metallic.

25. An intramedullary rod as claimed in any one of claims 17 to 24, in which the material is titanium.

26. An intramedullary rod comprising two spaced, elongate casing portions interconnected by portion having a lower density than the casing portions.

27. An intramedullary rod as claimed in claim 26, in which the lower density portion comprises a mesh.

28. An intramedullary rod as claimed in claim 26 or claim 27, in which the casing portions are further interconnected by means of a reinforcing structure.

29. An intramedullary rod as claimed in claim 28, in which the reinforcing structure comprises a plurality of beams.

30. An intramedullary rod as claimed in claim 29, in which the shape of the beams corresponds with part of a double helix running the length of the rod.

31. An intramedullary rod as claimed in claim 27 or any one of claims 28 to 30 when dependent on claim 27, in which the casing portions and the mesh comprise the same material.

32. An intramedullary rod as claimed in claim 31 when dependent on claim 28, in which the casing portions, the mesh and the reinforcing structure all comprise the same material.

33. An intramedullary rod as claimed in claim 32, in which the rod is casing portions, the mesh and the reinforcing structure are integral with one another.

34. An intramedullary rod as claimed in any one of claims 26 to 33, in which the spaced casing portions are arcuate when viewed in lateral cross section.

35. An intramedullary rod as claimed in claim 34 when dependent on claim 29, in which the beams interconnect opposing arcuate ends of the casing portions.

36. An intramedullary rod as claimed in claim 35, in which the mesh is exposed at opposing lateral surface regions of the rod between the arcuate ends of the casing portions and the beams.

37. An intramedullary rod formed entirely of non bio-absorbable materials and having at least one region that can be drilled whilst the rod is positioned intramedullary.

38. An intramedullary rod as claimed in claim 37, in which said at least one region comprises a portion of the rod having a lower density that at least one other portion of the rod.

39. An intramedullary rod having no predrilled holes for receiving fixation members and a region extending along its length adapted so that one or more holes for receiving fixation members can be formed therein when the rod is positioned intramedullary.

40. An intramedullary rod as claimed in any one of the previous claims, in which the outer profile of the rod is substantially circular or oval when viewed in lateral cross section.

41. An intramedullary rod as claimed in any one of the preceding claims wherein said rod is provided with a bore which extends lengthwise of the rod.

42. An intramedullary rod as claimed in any one of the preceding claims wherein the rod is a fixator for a proximal phalanx.

43. An intramedullary elongate rod as substantially described herein with reference to Figures 3a to 4, or Figure 5 or Figure 6, or Figures 7 and 8, or Figure 9 of the accompanying drawings.

44. A method of forming an intramedullary rod as claimed in any one of claims 27 to 38, the method comprising forming the rod from powdered metal using selective laser melting.

45. A method of implanting an intramedullary rod across a break in a bone, the method comprising forming at least one hole in the intramedullary rod whilst it is positioned intramedullary.

46. A method as claimed in claim 45, in which the at least one hole is formed using a laser.

47. A method as claimed in claim 46, in which the laser is an ultra short pulse laser.

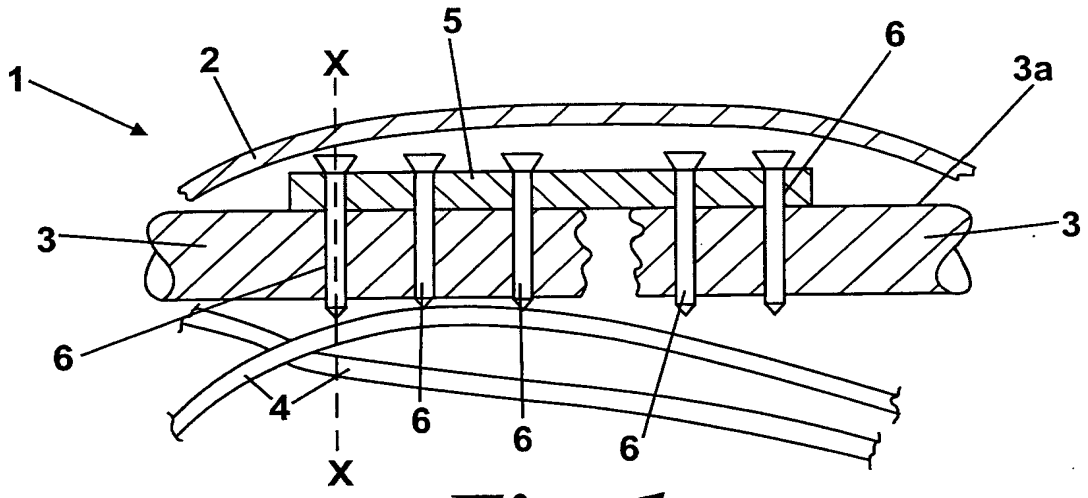


Fig. 1

(PRIOR ART)

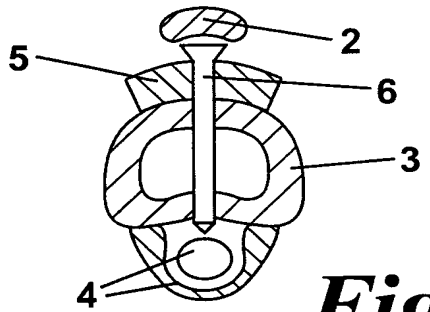


Fig. 2

(PRIOR ART)

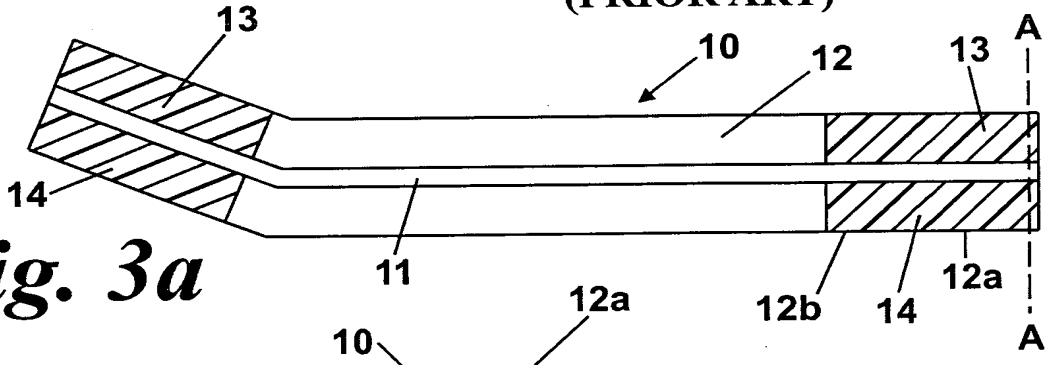


Fig. 3a

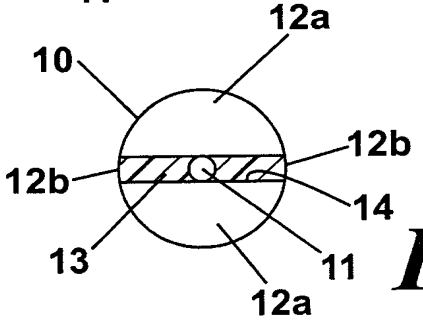
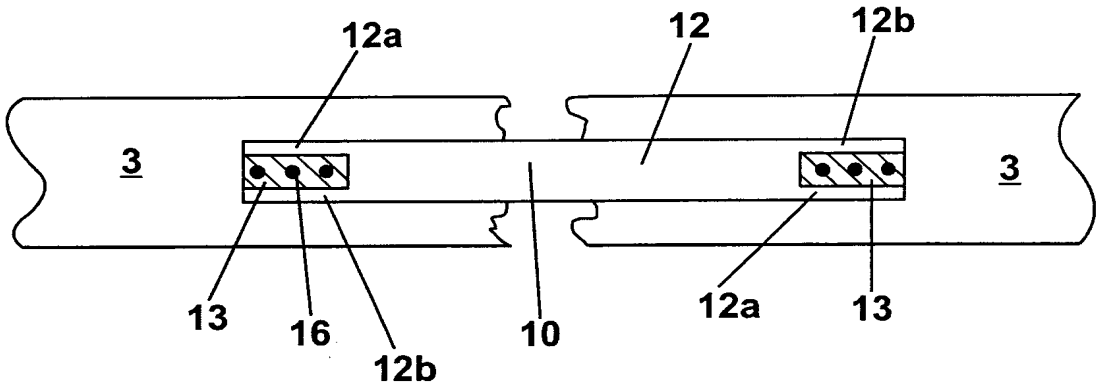


Fig. 3b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12a
13

Fig. 4

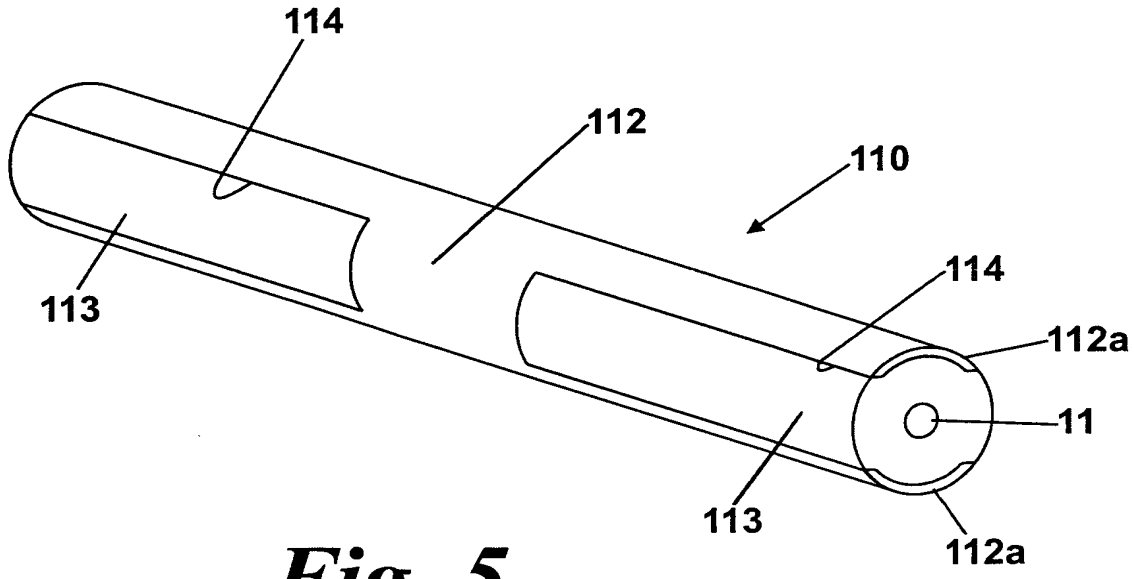
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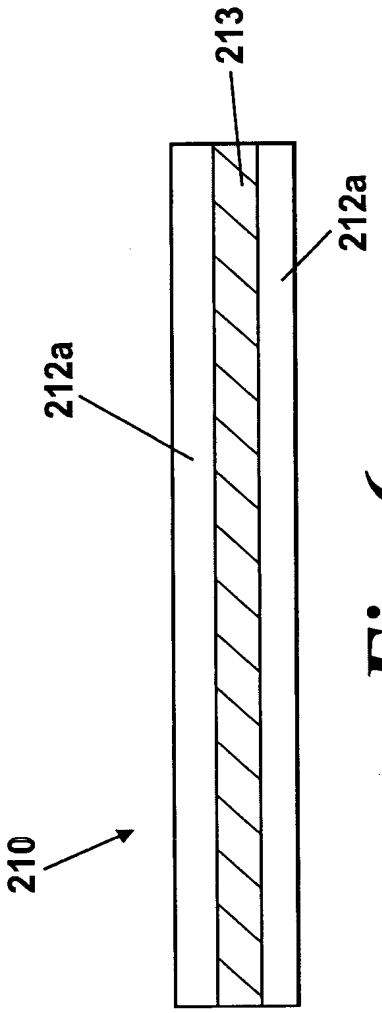
Fig. 5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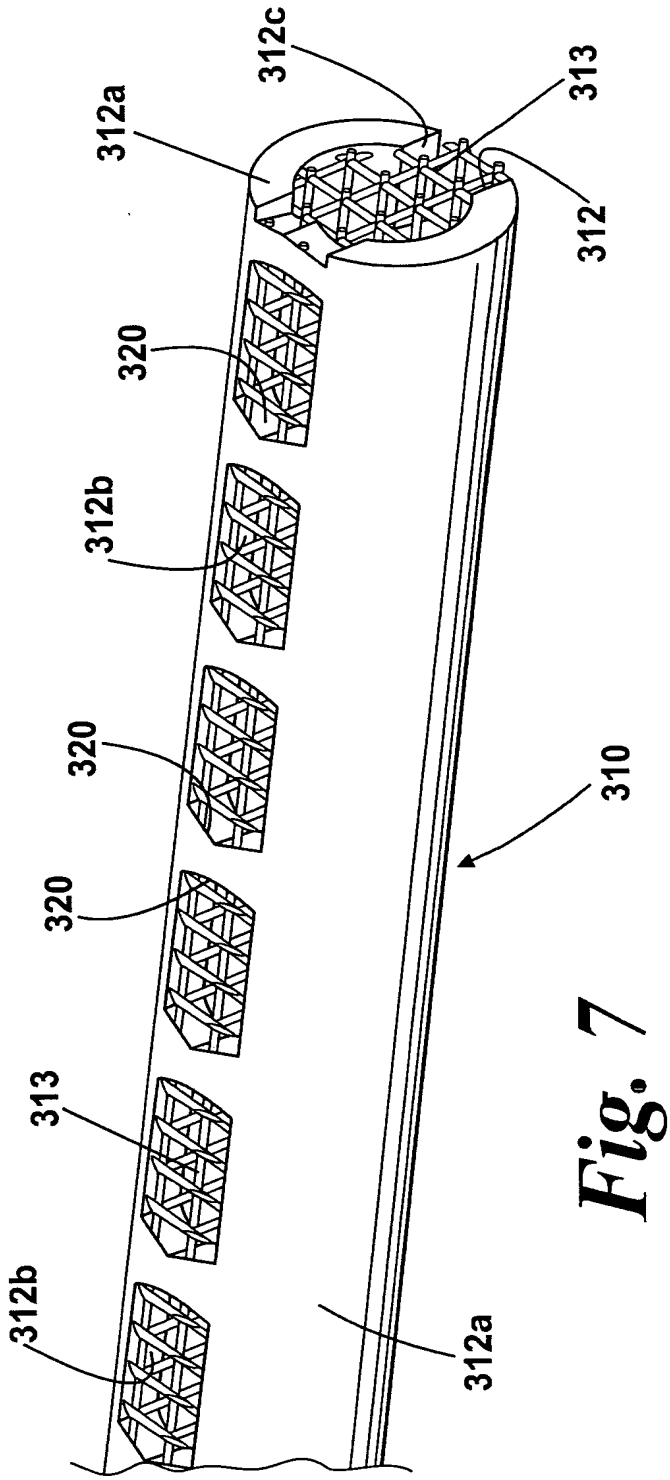
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Fig. 7

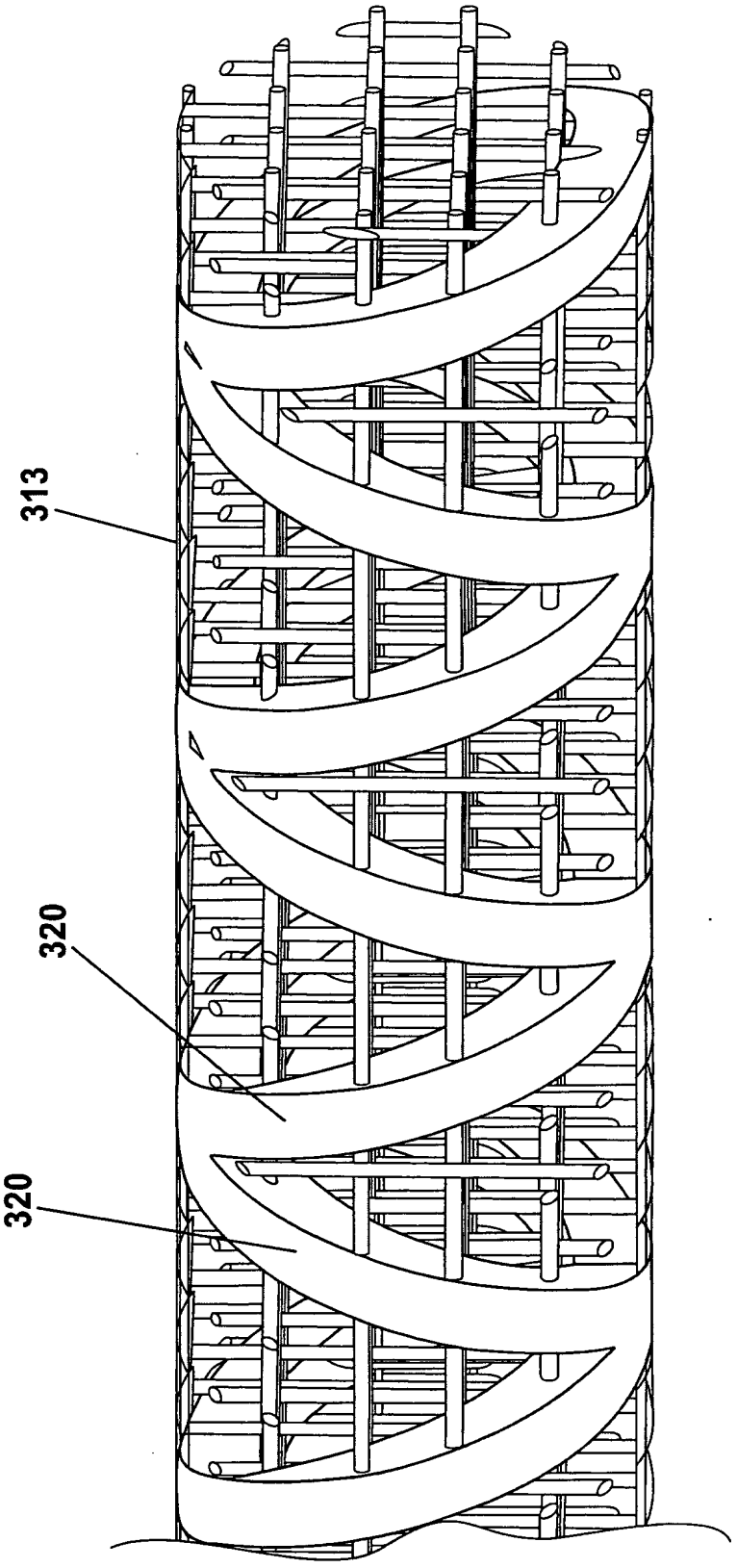

Fig. 8

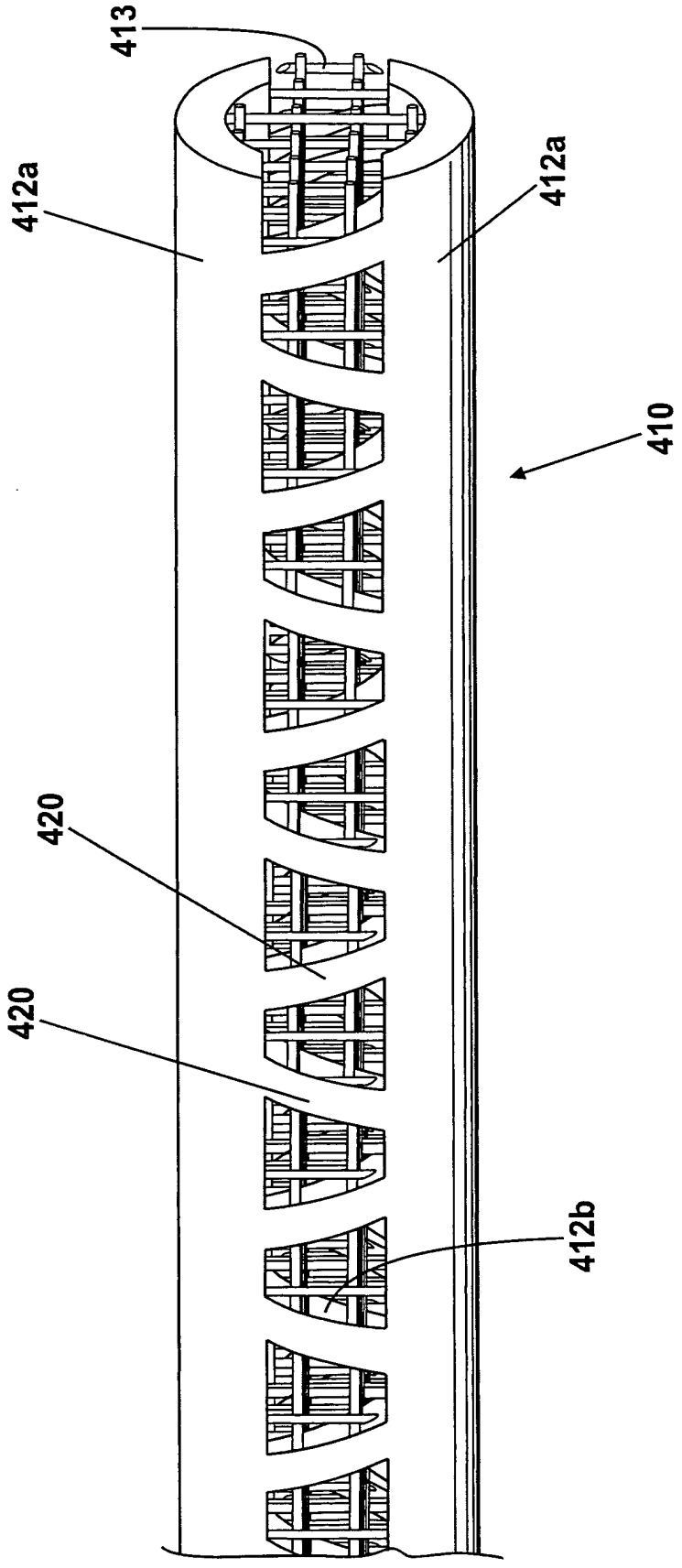

Fig. 9